K100414

Submission Date: 09.02.2010

2 510(k) Summary

Submitted by:	Merete Medical GmbH Alt Lankwitz 102 12247 Berlin, Germany
FDA Registration Number:	3002949614
Contact Person:	Emmanuel Anapliotis Merete Medical, Inc. 49 Purchase Street Rye, New York 10580 Phone: 914 967 1532
Proprietary Name:	ProToe™ EndoSorb™ Small Hammer Toe Pin
Common Name:	Arthrodesis Pin
Device Classification:	Screw, Fixation, Bone, Non-spinal, non-metallic (888.3040)
Product Code:	HWC
Proposed Regulatory Class:	Class II

Legally Marketed Devices To Which Substantial Equivalence Is Claimed:
Small Hammer Toe Pin, Biomet, Inc. (K021828); Resorbable Hammertoe Pin, Biomet, Inc. (K011137)

Intended Use:
The ProToe™ EndoSorb™ Small Hammer Toe Pin is indicated for proximal interphalangeal (PIP) joint arthrodesis.

Device Description:
The ProToe™ EndoSorb™ Small Hammer Toe Pin is made out of the bioresorbable EndoSorb™ material and is indicated for proximal interphalangeal (PIP) joint arthrodesis. EndoSorb™ is a polyerster derivative of L-Lactic and glycolic acids. Poly(L-lactide-co-glycolide) material (PLGA) degrades and resorbs in vivo by hydrolysis into L-lactic and glycolic acids, which are then metabolized by the body. The device has threads on one side and barbs on the other.

Substantial Equivalence:
The ProToe™ EndoSorb™ Small Hammer Toe Pin is similar to legally marketed predicate device listed above in that it shares similar indications for use, is manufactured from similar materials and incorporate similar technological characteristics. Any differences have been found to have no obvious effect on the performance, function, or intended use of the prosthesis.

Software Documentation:
No software is needed for the use of this device.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Room –WO66-G609
Silver Spring, MD 20993-0002

Merete Medical GmbH
% Merete Medical, Inc.
Mr. Emmanuel Anapliotis
49 Purchase Street
Rye, New York 10580

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Re: K100414
Trade/Device Name: ProToe™ EndoSorb™ Small Hammer Toe Pin
Regulation Number: 21 CFR 888.3040
Regulation Name: Smooth or threaded metallic bone fixation fastener
Regulatory Class: II
Product Code: JDW, HWC
Dated: June 25, 2010
Received: June 28, 2010

Dear Mr. Anapliotis:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set

forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please go to http://www.fda.gov/AboutFDA/CentersOffices/CDRH/CDRHOffices/ucm115809.htm for the Center for Devices and Radiological Health's (CDRH's) Office of Compliance. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

Mark N. Melkerson
Director
Division of Surgical, Orthopedic
and Restorative Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

K100414

Submission Date: 09.02.2010

1 Indications for Use Statement

Indications for Use

510(k) Number (if known):

Device Name: ProToe™ EndoSorb™ Small Hammer Toe Pln

Indications for Use:
The ProToe™ EndoSorb™ Small Hammer Toe Pln is indicated for proximal interphalangeal (PIP) joint arthrodesis.

Prescription Use X AND/OR Over-The-Counter Use _____
(Part 21 CFR 801 Subpart D) (21 CFR 807 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)